

Remarks

Claims 1-11 were pending in this application. By this amendment, claims 9-11 are canceled, as being drawn to a non-elected invention. Claims 1 and 6 have been amended. Claim 12 has been added. Support for the amendments and newly added claims 12-20 can be found throughout the specification, including at least on page 5, lines 7-10 and page 8, lines 1-6.

After entry of this amendment, **claims 1-8 and 12-20** are pending. No new matter is introduced by these amendments. Consideration and allowance of the pending claims are requested.

Applicants thank the Examiner for considering the Information Disclosure Statements submitted on June 23, 2006 and April 6, 2007.

Claim Rejection – 35 U.S.C. § 112, second paragraph

Claims 1-8 are rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

The Office alleges that the recitation of “ortholog” is indefinite, as allegedly the specification does not set forth any protein motifs or 3-dimensional structure to identify an ortholog of HIO30. Applicants assert that the term “ortholog” is clear and definite to one of skill in the art. However, solely to expedite prosecution, the term “ortholog” has been removed from claims 1 and 6, thereby rendering the present rejection moot.

The Office action also alleges that the phrases “high oil phenotype relative to control plants” and “altered oil content phenotype relative to control plants” are indefinite, as being allegedly unclear as to what is encompassed by the term “control plant.” Applicants assert that the term “control plant” is clear and definite to one of skill in the art. However, in efforts to expedite prosecution, claims 1 and 6 are amended herein to recite “a non-transgenic control plant...” Applicants believe that these amendments obviate the pending rejection.

Applicants request that the rejections under 35 U.S.C. § 112, second paragraph be withdrawn.

Claim Rejections under 35 U.S.C. §112, first paragraph:

(i) Written Description

Claims 1-8 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Office alleges that the present specification does not describe “any sequences that could be considered orthologs of HIO30.” The recitation of “or ortholog thereof” has been removed from claims 1 and 6. This amendment obviates the pending rejection for claims 1 and 6 as well as to all claims depending therefrom. To the extent this rejection might be applied to the amended claims, Applicants respectfully traverse.

Claim 1 as amended provides “a transgenic plant comprising a plant transformation vector comprising a nucleotide sequence that encodes or is complementary to a sequence that encodes a HIO30 polypeptide having at least 95% sequence identity with SEQ ID NO: 2, wherein the HIO30 polypeptide can alter the oil phenotype of the transgenic plant.” Claim 6 as amended provides a method of producing a high oil phenotype in a plant including “introducing into progenitor cells of the plant a plant transformation vector comprising a nucleotide sequence that encodes or is complementary to a sequence that encodes a HIO30 polypeptide having at least 95% sequence identity with SEQ ID NO: 2, wherein the HIO30 polypeptide can alter the oil phenotype of the transgenic plant.” Applicants assert that the recitation of at least 95% sequence identity provides a very predictable structure for the sequences employed in the claims for at least the reasons stated below.

The nucleic acid and amino acid sequence for HIO30 are provided (SEQ ID NO: 1 and 2, respectively). Those of skill in the art could readily envision all of the amino acid sequences that share at least 95% sequence identity to a polypeptide with the amino acid sequence provided in SEQ ID NO: 2. For example, one of skill in the art could identify amino acid sequences that are 95% identical to a SEQ ID NO: 2 by comparing a given sequence to the amino acid sequence

provided in SEQ ID NO: 2. See, for example, page 10, lines 3-18 of the specification. One of skill in the art could also determine if the identified amino sequence contained the desired functional activity (*e.g.*, alter oil phenotype of the plant), by methods known in the art and described in detail in the specification. See, *e.g.*, Example 1. Thus, Applicants submit that the knowledge and level of skill in the art at the time of Applicants' filing would allow a person of ordinary skill to envision the entire scope of the claimed invention, *i.e.*, a transgenic plant with high oil phenotype and method of producing such plant, in which the plant and method include a HIO30 polypeptide having at least 95% sequence identity with SEQ ID NO: 2 and that has the ability to alter the oil phenotype of the transgenic plant. Applicants were therefore in possession of the full scope of at least the amended claims, and provide a complete written description corresponding to this scope.

(ii) Enablement

Claims 1-8 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office alleges that these claims are not enabled because the specification is allegedly insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. In particular, the Office contends that the specification is not enabled "for any sequences that could be considered orthologs of HIO30." The recitation of "or ortholog thereof" has been removed from claims 1 and 6. This amendment obviates the pending rejection for claims 1 and 6 as well as to all claims depending therefrom. Applicants traverse the rejection to the extent that it may be applied to the amended claims.

Claim 1 as amended provides "a transgenic plant comprising a plant transformation vector comprising a nucleotide sequence that encodes or is complementary to a sequence that encodes a HIO30 polypeptide having at least 95% sequence identity with SEQ ID NO: 2, wherein the HIO30 polypeptide can alter the oil phenotype of the transgenic plant." Claim 6 as amended provides a method of producing a high oil phenotype in a plant including "introducing into progenitor cells of the plant a plant transformation vector comprising a nucleotide sequence that encodes or is complementary to a sequence that encodes a HIO30 polypeptide having at

least 95% sequence identity with SEQ ID NO: 2, wherein the HIO30 polypeptide can alter the oil phenotype of the transgenic plant.”

The Federal Circuit has repeatedly stated that enablement is not precluded by the necessity for some experimentation, so long as the experimentation is not undue. *In re Wands* 8 USPQ2d 1400 (Fed Cir 1988). In addition, a considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance in which the experimentation should proceed. *Id.* Applicants’ specification provides the guidance necessary to make and use the sequences encompassed in the instant claims. The specification provides the nucleotide and amino acid sequence for HIO30 and describes how to determine which HIO30 polypeptides are at least 95% identical to the disclosed HIO30 amino acid sequence. See, for example, page 10, lines 3-18. The specification also describes domains and functional activities which are desirable to conserve. See, for example, page 8, lines 1-21. Methods describing how to make polypeptide variants are also disclosed in the specification. See, for example, page 8, lines 21-27. Moreover, the claims require the HIO30 polypeptide to be able to alter oil phenotype in a plant, and the specification discloses assays for determining this activity. See, for example, Example 1. In order to practice the full scope of the amended claims, what is required is the identification or generation of a polypeptide that has at least 95% sequence identity to that of SEQ ID NO: 2, and determining if the polypeptide can alter the oil phenotype of the transgenic plant. As these methods of doing both are described in the specification, and/or well known in the art, they do not require undue experimentation. Applicants contend that claims 1 and 6 as well as claims depending therefrom are thus fully enabled.

The Office cites Doerks *et al.* (*TIG*, 14(6): 248-250, 1998), Brenner *et al.* (*TIG*, 15(4): 132-133, 1999), Borks *et al.* (*TIG*, 12(10) 425-427, 1996) and Broun *et al.* (*Science* 282: 1315-1317, 1998) as allegedly demonstrating the high level of unpredictability associated with altering a protein sequence with an expectation that the protein will maintain the same desired biological activity. However, nowhere do these references address HIO30 protein alterations and predicting activity in such proteins.

Finally, Applicants respectfully bring to the Office's attention to two decisions by the Board of Patent Appeals and Interferences: *Ex parte Sun*, Appeal No. 2003-1993 (B.P.A.I. January 20, 2004) and *Ex parte Bandman*, No. 2004-2319 (B.P.A.I. January 6, 2005). In both cases, the Board found that claims directed to sequences with 80% or 95% identity to a reference sequence were enabled because the supporting specifications provided a single reference sequence and an assay for activity of the encoded protein. As described above, the specification provides the nucleotide and amino acid sequence for HIO30 and assays for determining the oil content of a plant. Thus, based on these Board decision, Applicants' claims are enabled.

In light of the above, Applicants request that the enablement and written description rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

Newly added claims 12-20

Claims 12-20 are fully enabled, contain no new matter and satisfy the written description requirement for at least the reasons described above. Applicants believe that claims 12-20 satisfy all of the requirements of patentability and are in condition for allowance.

CONCLUSION

It is respectfully submitted that the present claims are in a condition for allowance. If any issues remain, the Examiner is requested to contact the undersigned attorney prior to issuance of the next Office action in order to arrange a telephone interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution and allowance of the claims.

Respectfully submitted,

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